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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,862	02/19/2004	Noriko Ban	HIRA.0132	1966

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,862	BAN ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/459,712.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 1-10. An action on the merits follows.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 02/19/2004 has been considered in full.

FOREIGN PRIORITY

Papers filed in parent case 09/459,712 for foreign priority are acceptable.

DRAWINGS

Drawings filed in 2/19/2004 are acceptable.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method for "detecting a degree of binding" in the preamble. However, as claim 1 does not recite any step directed to "detecting a degree of binding," it is unclear in what way steps (a)-(f) achieve the purpose of the preamble. Clarification is requested.

Claim 1, step (a) "immobilized on each different and separate predetermined position". There is insufficient antecedent basis for the "each different and separate...". Correction is requested.

Claim 1, step (c), recited the limitation "with the probes." There is lack of antecedent basis for this limitation. It is noted the claim 1 previously recites a "plurality of types of probes." Clarification is requested.

Claim 1, step (d), recited the limitation "the biopolymers bound to the probes." There is lack of antecedent basis for this limitation. It is noted that instant claim 1 does not previously recited a step directed to binding. Clarification is requested.

Claim 1, steps (d), (e), and (f), recite the limitation "amount of the probe" and "amount of the biopolymer." It is unclear whether "amount" refers to a concentration, an intensity, an emission, or otherwise. Clarification is requested.

Claim 1, step (f), recites the limitation "producing a value representing the degree of binding between the probes at each different and separate predetermined position." As there are no steps directed to averaging or normalization, it is unclear in what way the said "value" is representative of the "degree of binding" between the probes at "each different and separate predetermined position." Clarification is requested.

Claim 5 recites the limitation "wherein the amount of the probes is detected prior to the contacting step." It is unclear if this is an actual method step directed to "detection" which occurs before the said contacting step, or a further limitation of the said amount of the probes. Clarification is requested.

Claim 6 recites the limitation "wherein the amount of the biopolymers or the sample bound to the probes is detected prior to the contacting step." It is unclear if this is an actual method step directed to "detection" which occurs before the said contacting step, or a further limitation of the said amount of the biopolymers. Furthermore, as there is no previous step directed to "detecting the amount of the biopolymers or the sample bound to the probes," it is unclear in what way this limitation further limits the instant claimed method. Clarification is requested. Claims 2-4 and 7-10 are rejected as they depend either directly or indirectly from instant claim 1.

Claim 8 recites the limitation "the sample nucleic acids." There is lack of antecedent basis for "sample nucleic acids", as there are no nucleic acids in claim 1. Parent claim 1 recites biopolymers, but not nucleic acids. Correction is requested.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being as being anticipated by Walt et al. (US 6,023,540, Filed March 14, 1997).

Walt et al. teach a microsphere-based analytical system to identify chemical functionality using fluorescent dyes and optical fiber bundles [Abstract]. More specifically, Walt et al. teach the following aspects of the instantly claimed invention:

- Optical fiber wells (i.e. substrate) on which microbeads are attached [Col. 4, lines 4-9 and Ref. Claim 39], wherein the microbeads have predetermined positions [Fig. 7] and contain fluorescent reporter dyes (i.e. fluorescent labels) [Col. 5, lines 40-50], as in instant claim 1, step a, and instant claim 2.
- Probe sequence attached to a microsphere, and a fluorescent dye molecule attached to a target sequence (e.g. nucleic acid) [Col. 10, lines 5-10], as in instant claim 1, step b.
- Contacting target analyte in a sample with a substrate comprising microspheres [Ref. Claim 39], as in instant claim 1, step c.

- The detection of the microspheres at any position within the optical fiber wells [Col. 12, lines 5-15], which is a teaching for detecting an amount of probes at different positions, as in instant claim 1, step d, and instant claim 5.
- A genosensor wherein subpopulations of microspheres are affixed to antibodies (i.e. proteins) and fluorescent levels are detected and displayed on a micrograph [Col. 15, lines 16-35], as in instant claim 1, step c and e, and instant claims 4 and 9.
- Optical signature values representing the degree of binding between probes and target analytes based on ratios [Col. 13, lines 50-60], as in instant claim 1, step f, and instant claims 6 and 7.
- A two-dye system with distinct emission wavelengths [Col. 6, lines 30-40], as in instant claim 3 and 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being made obvious by Schena et al. (Proc. Natl. Acad. Sci., 1996, Vol. 93, p.10614-10619), in view of Tyagi et al. (Nature Biotechnology, 1996, Vol. 14, p.303-308).

Schena et al. teach a method for detecting a degree of binding between a plurality of labeled probes and a microarray substrate using a two-color hybridization assay [Abstract]. More specifically, Schena et al. teach the following aspects of the instantly claimed invention: A DNA gene chip substrate for binding a plurality of probes [Abstract], as in instant claims 1 and 10; binding of mRNA samples labeled with two distinct fluorescent probes to the gene chip [p.10615, Results], as in instant claim 1; expression ratio values from two hybridizations based on a difference [Fig. 2 and Table 1], as in instant claim 1, step f.

Schena et al. do not specifically teach microarray substrates comprising immobilized probes with fluorescent labels, as in instant claim 1.

Tyagi et al. teach the use of molecular beacon probes comprising fluorophone-quencher pairs that fluoresce upon hybridization to a target [Fig. 1], as well as detection methods [p. 305, Col. 1, ¶ 2]. Tyagi et al. also teach the use of multiple molecular beacons simultaneously for detection of many different targets in the same solution [p.307, Col. 2, ¶3]. Tyagi et al. also teach the use of molecular beacons immobilized to different positions on the surface of a reaction vessel or 2-D array for carrying out extensive analysis of genomic regions [p.307, Col. 2, ¶ 4].

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to combine the molecular beacons of Tyagi et al. with the two-color hybridization assay of Schena et al., where the motivation would have been to use a 2-D array of molecular beacons immobilized to a surface for improved diagnosis of disease and

discriminating closely related pathogenic organisms in clinical samples [Tyagi et al., p.307, Col. 2, ¶ 4 and 5], resulting in the practice of the instant claimed invention. One of skill in the art would have had a reasonable expectation of successfully using the molecular beacons of Tyagi et al. with the two-color hybridization assay of Schena et al., as both teach fluorophore systems for probe detection.

Obviousness-Type Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 7-12 of US 6,775,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because of

the broadly encompassing scope of the instantly claimed invention causing the inventions to have overlapping embodiments. The instant claims and those of US 6,775,621 recite the same method steps, with minor variations. For example, Claim 1 of the instant application recites a method of detecting "degree of binding," whereas claim 1 of US 6,775,621 is directed to a method of detecting "degree of hybridization." It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to detect degree of hybridization between probes and biopolymers, as hybridization is a well-known method of binding. This is an obviousness-type double patenting rejection because the conflicting claims have in fact been patented.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
8/14/06